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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/036,568	WILLSON ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-45 and 47-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *37,42,43 and 47* is/are allowed.

6)☒ Claim(s) *38-41, 44-45, 48-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/7/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed 10/1/07 has been entered. Claims 37-45 and 47-50 are pending in the application. Claims 1-36, 46 and 51 have been cancelled. Applicant's arguments have been fully considered and are addressed below.

2. The supplemental reply filed on 12/12/07 was not entered because supplemental replies are not entered as a matter of right except as provided in 37 CFR 1.111 (a)(2)(ii). The Declaration of Nicos A. Nicola filed under 37 CFR 1.132, on 12/12/07, has not been considered because it was not timely filed and is clearly not limited to placement of the application in condition for allowance.

Claim Rejection, 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 41 and 45 remain rejected under 35 U.S.C. 112, second paragraph (see 6/3/07 and 2/28/06), as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments:

Applicants traverse examiners rejection of claims 41 and 45 as pertaining to "soluble form" and mature form". Applicants argue methods for predicting the site of cleavage between a signal sequence and the mature protein were known prior to the present invention, and that based on the information provided in the specification those

skilled in the art would be able to make a **"reasonable determination"** of the starting and ending amino acid residues of a soluble form" and "mature form" of NR4. Applicants further argue that example 6 of the specification (page 37) and Figure 1 defines the various domains of murine NR4 including a signal sequence. Applicants also argue that that SEQ ID NO:4 is the human homolog of murine R4 with 75% similarity at the amino acid level. Applicants also argue that the Milouex et al reference (FEBS Letters 401, 163-166, 1997) describes methods for determining the signal sequence cleavage position and the transmembrane region of human Il13Rα. Applicant's arguments have been fully considered but they are not found persuasive. **The specification does not define the terms "soluble form" or "mature form". The art does not define "soluble form" or "mature form" of NR4.** Applicants argue those skilled in the art would be able to make a **"reasonable determination"** of the starting and ending amino acid residues of a soluble form" and "mature form" of NR4. This statement begs the question, what is considered a **"reasonable determination"** of the starting and ending amino acid residues of a soluble form" and "mature form" of NR4. The claims are drawn to specific species of protein which require the exact knowledge of the amino acids that make up the signal sequence of the human NR4 and those that sequences that make up the soluble protein and mature protein. Although signal sequence for the murine NR4 is disclosed in the specification the signal sequence of human NR4 was not known at the time filing of instant application. The sequences of human and murine NR4 have 75% similarity but the first 26 amino acids on murine NR4 (signal sequence of murine NR4) is only 61.5% identical to human NR4. Based on the disclosure no determination can be made that both murine and human NR4 have the same signal sequence.

Comparison of the first 26 amino acids of human and murine NR4:

Human M **E** **W** P A **R** L **C** **G** G **G** **G** **G** A **P** T E **T** E N L C T V I W

Murine M **A** **R** P A **L** L **G** **E** G **Q** **V** **A** A **A** T E **V** E N L C T I I W

The question arises did the prior art conclusively predict the signal sequence and the sequence of the mature and soluble form of the NR4 without ambiguity so as to allow the metes and bounds of the claim to be determined. Applicant has provided no showing that all the methods in the prior art would predict the same signal sequence for claimed polypeptide. The algorithms used to predict the signal sequence are not disclosed. The default parameters used to search for specific sequences using these algorithms are not disclosed. Different programs and different default parameters will different results. These in turn will have a dramatic effect on the metes and bounds of the claim. Contrary to applicants arguments the Miloux article does not disclose the algorithm used to determine the signal sequence of human NR4. Further Miloux states, "The amino acids corresponding to the **predicted** signal peptide are indicated with dashes", See Fig. 1. Miloux predicted a signal sequence for human NR4. Applicants, at the time of filing instant application, neither predicted a signal sequence for human

NR4 nor disclosed the algorithm that would determine what the signal sequence is.

Further, even if any of the methods known in the art are used to study the structure of the claimed invention there is guarantee they will all give the same answer as to structure of the "soluble form" or "mature form". For example the default parameters used to test the methods is not disclosed. The point being there will still be ambiguity as to the exact nature of the "soluble form" or "mature form". If the exact size of the "soluble form" or "mature form" cannot be defined as it relates to the polypeptide disclosed in SEQ ID NO:4 then the metes and bounds of the claim cannot be defined. The rejections of claims 41 and 45 are maintained for reason of record in the previous Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 38-41, 44-45 and 48-50 remain rejected under 35 U.S.C. 112, first paragraph, for reason of record (3/27/07 and 2/28/07), because the specification, while being enabling for the isolated polypeptide of SEQ ID NO:4, wherein said polypeptide binds at least one of human Il-13 and human Il-4 does not reasonably provide enablement for polypeptides that comprises fragments of SEQ ID NO:4 without a defined biological activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicants' arguments are addressed below (section 6).

5. Claims 38-41, 44-45, 48-50 remain rejected under 35 U.S.C. 112, first paragraph, (3/27/07 and 2/28/07) as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention . Applicants' arguments are addressed below (section 7).

Applicant's arguments:

Applicants argue that claim 38 has been amended to recite a fragment of SEQ ID NO:4 and that and that the specification provides guidance for said fragments. Applicant's arguments have been fully considered but are not found persuasive for reason given below

6. Enablement

Claims 38-41, 44-45, 48-50 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated polypeptide of SEQ ID NO:4, wherein said polypeptide binds at least on of human Il-13 and human Il-4 does not reasonably provide enablement for polypeptides that comprise fragments of SEQ ID NO:4 without a defined biological activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While the person of ordinary skill in the art would, in light of the specification be able to isolate the polypeptide disclosed in SEQ ID NO:4 the scope of the claims, which encompass derivatives (polypeptides comprising a fragment) of undefined structure and function are not enabled by the disclosure. A fragment is interpreted to be any part of the polypeptide disclosed in SEQ ID NO:4. Applicant argues that a fragment of the polypeptide of SEQ ID NO:4 cannot be understood to mean on amino acid, but has provided no support for said statement. Without support for a clear definition for the "fragment", the examiner interprets it to be any part of SEQ ID NO:4, i.e. can be 1 amino acid, 2 consecutive amino acids present in SEQ ID NO:4, 3 consecutive amino acids present in SEQ ID NO:4, etc. Further polypeptides comprising fragments of the polypeptide of SEQ ID NO:4 and having no defined function are not enabled. The disclosure does not teach how to make such functional derivatives or other such polypeptides encompassed by the claims. The disclosure does not teach how to use such non-functional derivatives or other such polypeptides encompassed by the claims which may be inactive or have activities different to that of NR4. The claims encompass every polypeptide known, or yet to be isolated whether it is functional or not. Page 7, lines 3 of the specification discloses the derivatives may be "functional or not" and may be "parts, fragments or portions" of NR4. The claims encompass a polypeptide comprising a fragment of the polypeptide of SEQ ID NO:4. A fragment can even be an ion, a single amino acid or a few amino acids. A fragment can be as little as two amino acids. Therefore the claims encompass every polypeptide known to man, applicants are not enabled for this scope. The claims encompass no functional language.

Applicant has not disclosed how to use derivatives that do not bind Il-13 or Il-4. Applicant has not disclosed how to use derivatives with no activity.

Although derivatives of IL-13 receptor (polypeptides comprising fragments of the polypeptide of SEQ ID NO:4) can be made, said derivatives carry no weight in terms of structure and function and encompasses numerous alterations and reads on unrelated polypeptides. Also polypeptides defined only by comprising "part", which can be one amino acid, carry no weight in terms of structure and function and encompasses numerous alterations and reads on unrelated polypeptides. Instant specification does not teach which particular amino acids (parts or fragments) are critical for the functionality of the claimed polypeptide i.e. the critical feature of the invention as it relates to function is not disclosed. Therefore structurally deficient polypeptides containing random mutations would be expected by the skilled artisan to result in molecules encoding inactive or unrelated proteins or polypeptides. For example, Rudinger (see previous office action) states that "it is impossible to attach a unique significance to any residue in a sequence. A given amino acid will not by any means have the same significance in different peptide sequences, or even in different positions of the same sequence". Rudinger further states on page 6 that "the significance of particular amino acid sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study". Therefore, the lack of guidance provided in the specification as to what minimal structural requirements are necessary for functional protein would prevent the skilled artisan from determining whether any modification, mutation of SEQ ID NO:4

or other protein encompassed by the claims could be made which retains the undisclosed activity of the claimed invention, because any random mutation or modification manifested within said protein itself would be predicted to adversely alter its biologically active 3-dimensional conformation, without undue experimentation to determine otherwise.

The fact remains that the activity of the claimed polypeptides or the actual structure of the polypeptide cannot be envisioned any better when the possible choices are narrowed from all possible molecules to all possible molecules that comprise fragments or parts of SEQ ID NO:4. For example, if one skilled in the art were to make a polypeptide with 90% identity to the reference amino acid sequence SEQ ID NO:4, he would be no more able to say whether it inhibits IL-4 binding if the polypeptide was only 10% identical to the reference polypeptide sequence. Nor would he be able to say whether the sequence existed in nature. The specification does not provide any information on what polypeptides apart from those disclosed above are necessary and sufficient for a functional activity. The specification also provides no teachings on what amino acid sequence modifications, e.g. insertions, deletions and substitutions, would be permissible in an active polypeptide that would improve or at least would not interfere with the biological activity or structural features necessary for the biological activity and stability of the protein. Therefore one cannot predict which receptor molecules comprise a biologically active product encompasses by the claims

7. Written description

Claims 38-41, 44-45, 48-50 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims are drawn to polypeptide, comprising a fragment of SEQ ID NO:4 with no disclosed activity . The claims either provide a) no functional limitation and b) meaningless structural limitation (comprising a fragment of SEQ ID NO:4).. The claims encompass every polypeptide known, or yet to be isolated whether it is functional or not. Page 7, lines 3 of the specification discloses the derivatives may be "functional or not" and may be "parts, fragments or portions" of NR4. The phrase "comprising a fragment of SEQ ID NO:4 does not sufficiently describe the structure or function of the polypeptides covered by the name. Every protein known to man comprises a part of SEQ ID NO:4 (i.e. a single amino acid) since they share at least one common amino acid. The polypeptides encompassed by the claims have no disclosure of the critical technical feature of the claimed invention or its relationship to function. The critical technical feature encompassed by the polypeptide and how it relates structurally and functionally to the polypeptides of SEQ ID NO:4 is not disclosed. Thus, the claims are drawn to a genus of molecules that vastly varies in structure and function. It would take undue experimentation to discover the polypeptides encompassed by the claim. The specification does not provide any information on what polypeptides apart from SEQ ID

NO:4 are necessary and sufficient for a functional activity. The specification also provides no teachings on what amino acid sequence modifications, e.g. insertions, deletions and substitutions, would be permissible in an active receptor polypeptide that would improve or at least would not interfere with the biological activity or structural features necessary for the biological activity and stability of the protein. Therefore one cannot predict the molecules required or a biologically activity. Rather one must engage in case-to-case painstaking experimental study to determine active variants. Consequently, excessive trial and error experimentation would have been required to identify the necessary polypeptide derivatives/variants since the structure of said derivatives/variants could not be predicted.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. Apart from the polypeptides of SEQ ID NO:4 there is no disclosure of a particular portion of the structure of other molecules that must be conserved and have the functionality of the claimed genus. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

When one is unable to envision the detailed constitution of a complex chemical compound having a particular function, such as a polypeptide, so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the polypeptide has been isolated. Thus, claiming all polypeptides that achieve a result without defining what means will do so is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. The claims do not recite a structural relationship between the claimed polypeptide in terms of its structure and related specific function.

Even if Applicant added an functional limitation to the claims the fact remains that polypeptides with a particular activity or the actual structure of the Il-13 polypeptide cannot be envisioned any better when the possible choices are narrowed from all possible molecules to all possible molecules that for example comprise a part of the polypeptide of SEQ ID NO:4. For example, if one skilled in the art were to make a polypeptide with 90% identity to the reference amino acid sequence SEQ ID NO:4, he would be no more able to say whether it inhibits an undefined cellular receptor activity than if the polypeptide was only 10% identical to the reference polypeptide sequence. Nor would he be able to say whether the sequence existed in nature. In instant case the term "derivative" encompasses billion of compounds.

The specification does not provide any information on what polypeptides apart from the polypeptide of SEQ ID NO:4 are necessary and sufficient for a functional activity. The specification also provides no teachings on what amino acid sequence

modifications, e.g. insertions, deletions and substitutions, would be permissible in an active IL-13 receptor polypeptide that would improve or at least would not interfere with the biological activity or structural features necessary for the biological activity and stability of the protein. Therefore one cannot predict which mutation would result in active Il-13 receptor molecules required for a particular biologically activity. Rather one must engage in case-to-case painstaking experimental study to determine active derivatives/variants. Consequently, excessive trial and error experimentation would have been required to identify the necessary derivatives/variants since the structure of said derivatives/variants could not be predicted.

The specification discloses only one putative amino acid sequences, SEQ ID NO:4 for a polypeptide having the necessary properties of binding IL-13 and/or IL-4 and provides no guidance on obtaining other functional molecules, which would be suitable, even if an activity was added to the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 , clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she) invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the

method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird,* 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF'S were found to be unpatentable due to lack of written description for that broad class.

Therefore, only the use the isolated polypeptide disclosed by SEQ ID NO:4 but not the full breadth of the claims meets the written description provision of 35 U.S.C.j112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1 115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 38, 44, 45 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Kiyoshi et al (US PATENT 5453491, see previous office action).

Kiyoshi discloses a polypeptide (SEQ ID NO:6) comprising a fragment (amino acid) of SEQ ID NO:4 which can be in recombinant form or comprising a pharmaceutically acceptable carrier. Therefore the disclosure of Kiyoshi meets the limitations of claims 38, 44, 45 and 48 absent evidence to the contrary.

Applicant's arguments:

Applicants argue that in light of the specification, those skilled in the art would not interpret the term "fragment" of SEQ ID NO: 4 to include simply an amino acid. Applicant's arguments have been fully considered but they are not found persuasive.

To put applicants arguments in perspective the first two paragraphs on page 7, lines 1-13 are recited below in their entirety:

"Reference herein to "recombinant haempoietin receptor", "NR4", "IL- 13 receptor" or "IL- 13" receptor α-chain" includes reference to **derivatives** thereof such as **parts, fragments, portions,** homologues, hybrids or **analogues** thereof. The **derivatives may be functional or not** or may be non-functional but immunologically interactive with antibodies to all or part of the receptor. Derivatives of the receptor also cover agonists or antagonists of receptor-ligand interaction. Function is conveniently defined by an ability of N-R4 to interact with IL-13 or its derivatives or for soluble NR4 to compete with IL-13-induced activities of certain cells. Particularly preferred derivatives contemplated by the present invention include derivatives of IL-13 receptor α-chain which are capable of binding IL-13 with high affinity or with IL-13 and IL-4 with high affinity; derivatives also encompass chimeric molecules such as between IL-,13 receptor n-chain and, for example, IL--4 receptor a-chain which also bind IL-13 with high affinity.

As disclosed in the specification a derivative of NR4 includes a part, fragment, portion or analogue of NR4. The derivatives may be functional or not. There is nothing in the specification that argues away from a single amino acid being interpreted as a part, fragment or portion of NR4. therefore the rejection is maintained.

7. Claims 37, 42, 43, 47 are allowable.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nirmal S. Basi
Art Unit 1646

CHRISTINE J. SAOUD
PRIMARY EXAMINER